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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,235	06/02/2000	Tayyaba Hasan	10284016001	6500

20999 7590 12/03/2003

FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER
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RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/586,235

Applicant(s)

HASAN ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 22 September 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Note of Explanation.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Note of Explanation.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-5, 7-16, and 18-28.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18.
10. ☒ Other: See Continuation Sheet

Continuation of 10. Other: See attached Note of Explanation; See attached PTO Form 892 and Letter of November 24, 2003. .

### Not of Explanation

1. The proposed amendment filed September 22, 2003 in Paper No. 20 is acknowledged and has been placed in the file; however, the proposed amendment to the claims will not be entered for the following reasons:

Entry of the proposed amendment would raise new issues that would require further consideration and search. For example, entry of the proposed amendment to claim 1 would necessitate a determination of whether, and to what extent, the prior art of record anticipates under 35 USC § 102(e), or renders obvious under 35 USC § 103(a) the claimed invention. Applicants have remarked that the amendment would obviate the rejection of the claim under 35 USC § 102(e) as being anticipated by US Patent No. 5,784,162-A, because, as would be amended, claim 1 would recite the limitation that a cancerous cell in a subject be induced to differentiate, while the prior art teaches a method in which a cell is induced to differentiate *in vitro*, rather than in a subject. Accordingly, entry of the amendment would necessitate a determination of whether or not the prior art anticipates claim 1, as would be amended; and if the prior art does not explicitly teach the limitation that the method can comprise the step in which a cancerous cell in a subject is induced to differentiate, it would be necessary to determine whether or not the prior art provides the suggestion and motivation to induce differentiation in a cancerous cell in a subject. If not, it would be necessary to search the prior art to determine if the prior art teaches or provides the suggestion and/or motivation absent in the prior art presently of record.

Accordingly, entry of the proposed amendment is not deemed to place this application in better form for appeal by materially reducing or simplifying the issues for appeal.

2. Regarding the declaration under 37 CFR § 1.132 by Tayyaba Hasan, Bernhard Ortel, and Edward Maytin filed September 22, 2003 in Paper No. 21, the merit of the

declaration has been considered. However, at present, the declaration is not deemed sufficient to overcome the rejection of the claims under 35 USC § 103(a) for the reason set forth in section 17 of the Office action mailed May 20, 2003 (Paper No. 17). Although Applicants have stated in Paper No. 20 that Ortel et al. is not prior art under 35 USC § 102(b), because the priority date of the application is June 3, 1999, and the publication date of Ortel et al. is June 10, 1998, Applicants have provided no factual evidence to support this statement, and the Examiner was unable to confirm Applicants' statement using available resources. To the contrary, Julia Maidment of the British Journal of Cancer Editorial Office states in a letter dated November 24, 2003 that subscribers of the journal could have received the June 1998 issue as early as May 22<sup>nd</sup> or May 23<sup>rd</sup> of 1998, which provides evidence suggesting that the disclosure of the prior art was made publicly available more than one year prior to the date of application. Applicant is invited to submit objective evidence that the publication was not mailed by the publisher and/or not received by subscribers prior to the date of application.

3. The merit of Applicants' arguments traversing the grounds of rejection of the claims under 35 USC § 112, first paragraph cannot be considered without entry of the proposed amendment to the claims, as it appears that any merit relies upon entry of the proposed amendment.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
November 25, 2003

<sup>A</sup>  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600